staff hours than patients prescribed other competing medications. One such study was Olanzapine Treatment of Psychotic and Behavioral Symptoms in Patients With Alzheimer Disease in Nursing Care Facilities, *Archives of General Psychiatry*, Vol. 57, pg. 968 (Oct. 2000) See Exhibit "N." Plaintiff-Relator and other Lilly LTC sales representatives were told to point directly to pg. 971 of this study and read:

> "A statistically significant reduction in caregiver distress, measured by the sum of the Occupational Disruptiveness scores for Agitation/Aggression, Hallucinations, and Delusions (Core Disruptiveness) was seen for patients treated with 5 mg/d of olanzapine... Caregivers of patients treated with 5 mg/d of olanzapine also had similar reductions in Occupational Disruptiveness associated with Anxiety, Appetite and Eating Disorders, Delusions, Depression/Dysphoria, and Hallucinations items."

116. Lilly LTC sales representatives were taught to create "action" in nursing homes by marketing Zyprexa's "calming" effect. In truth, this was Lilly's thinly-veiled marketing of Zyprexa as an effective **chemical restraint** for demanding, vulnerable, and needy patients.

117. In addition, Plaintiff-Relator's manager disseminated a form letter to the representatives under his supervision and control that touted Zyprexa as providing superior efficacy and safety when compared to placebo and significantly reduced caregiver burden at a dose of 5 mgs daily. See Exhibit "B." This statement was "supported" by a footnote citing a study that ostensibly supported this mendacious marketing of Zyprexa as a chemical restraint. *Id.*

118. The form letter also expressed the medical opinion that the 5 mg. dose of Zyprexa should be administered at 5 pm. *Id.* This was a Lilly-trained "5 at 5" slogan which translated essentially referred to give your patients 5 mg. of Zyprexa at 5 pm and they will sleep through the night eliminating the disruptive late night conduct demanding of caregiver time.

119. Atypical antipsychotics are powerful medications, laden with serious treatment-emergent side effects. Zyprexa is a dangerous drug even when prescribed for on-label use. It is even more dangerous for the elderly. Zyprexa and the other atypical

antipsychotics have not received FDA-approval to treat the elderly because of atypicals' serious risk of harm and the lack of scientific evidence of its safety and efficacy in this population.

120. On April 11, 2005, the FDA issued a public health advisory to alert health care providers, patients, and patient caregivers of its determination based upon clinical studies that using Zyprexa or the other atypicals to treat behavioral disorders in elderly patients with dementia is associated with increased mortality. The FDA's examination of the specific causes of these deaths revealed that most were either due to heart related events (e.g., heart failure, sudden death) or infections (mostly pneumonia).

121. Accordingly, the FDA required Lilly to amend Zyprexa's label to include a "black box warning" of this deadly side effect. A 'black box' designation is an FDA-recommended/mandated warning based upon clinical research studies, for certain drugs that may cause serious and potentially life-threatening side effects. The FDA requires that a black box warning be placed on the labeling or literature of a prescription drug, or in literature describing it. It is the strongest warning the FDA requires.

122. Because of Lilly's promotion of Zyprexa's somnolence side effect as an attribute of the drug, patients were intentionally medicated with incapacitating antipsychotic agents such as Zyprexa to control patient behavior, "restore calm" and reduce the time needed to be spent to treat patients, especially the those patients who required burdensome, time intensive care, as well as those patients who demonstrated "oppositional" and "defiant" behavior.

123. The use of atypical and typical antipsychotic drugs to control the behavior of elderly nursing home residents who are not psychotic constitutes an **unlawful chemical restraint**. Lilly's unlawful and unethical promotion of the use Zyprexa, off-label, as a **chemical restraint** resulted in patients being restrained in a zombie-like state, unable to complain or object. Prescriptions were medically unnecessary

124. The State of California's healthcare programs would not have paid prescription drug reimbursement claims caused to be submitted by Lilly's mendacious and

unlawful marketing of Zyprexa's somnolence side effect had it known the truth.

125. As part of the Zyprexa sales campaign, Lilly disseminated Zyprexa LTC Implementation Guides to its LTC sales representatives. Lilly created a LTC Implementation guide specifically to roll out each new year's version of Lilly's LTC patient profile. See eg Exhibit "E."

126. Lilly's LTC detail aid was a LTC stereotypical patient - an elderly patient representing the agitated, hostile geriatric patients LTC physicians treat everyday. "Rose" was the detail piece used by LTC sales representatives to represent the angry and hostile elderly patient complaining of symptoms such as anxiousness, irritability, mood swings, and disturbed sleep. See e.g. Exhibit "D."

127. The "Rose Jackson" ("Rose") detail aid contained only conspicuously printed wording like "Agitation," "Depressive Symptoms," "Aggression," Irritability," and "Sleeplessness" calculated to imply that Zyprexa was indicated for the treatment of such symptoms. *Id.* The top of the front page conveyed the message "Helping you bring dignity to patients' lives." *Id.* Nowhere on this Rose detail aid did Lilly explicitly disclose that Zyprexa's FDA-approval was limited to the treatment symptoms of schizophrenia and bipolar mania and not the other generic symptoms highlighted in print on the detail aid (i.e. sleeplessness, irritability, depressive symptoms). *Id.*

128. The detail piece featured a large color picture of "Rose," an elderly woman composed to appear agitated and combative. *Id.* Lilly's strategy goal for the Rose detail piece was to "encourage doctors to try Zyprexa in patients similar to the one we profile, Rose Jackson. In this way, doctors can see for themselves that Zyprexa stabilizes symptoms and behaviors safely."

129. "Rose" was designed to personalize the sales representative's promotion of Zyprexa as the wonder drug to "calm" difficult patients and to reduce patient treatment time. Plaintiff-Relator was instructed to show this image to clients to reinforce the marketing message that Zyprexa can treat his or her angry, agitated and difficult patients.

130. Lilly even disseminated along with the Rose detail aid the marketing

message the sales representative was expected to learn verbatim and then deliver during LTC physician sales calls, which Plaintiff-Relator still recalls to this day. Lilly trained its sales representatives to show the Rose detail aid to physicians and deliver a verbatim sales pitch probe recommending that the physician's patients like Rose are indicated for treatment with Zyprexa and would benefit from commencing a Zyprexa regimen. By way of example, Plaintiff-Relator and other sales representatives would ask leading questions to physicians relayed in the LTC Implementation Guide, such as, "Doctor, does it make sense to use Zyprexa as a first choice for a patient like Rose, since Zyprexa helps to safely stabilize symptoms and behaviors such as agitation, anxiety, hostility, delusions, and resistance to care?" See Exhibit "E."

131. Future iterations of the Zyprexa LTC Implementation Guides similarly helped deliver the message that Zyprexa should be prescribed to treat moods, behaviors and symptoms. By way of example, in the January 2003 "Rose" Detail Aid, Lilly describes to sales representatives, including Plaintiff-Relator, that on the detail aid's cover, "there is also the addition of a couple more mood symptoms, which is to emphasize our unique ability in treating mood." See Exhibit "F."

132. When detailing the Zyprexa 2003 LTC Rose detail piece, sales representatives, including Plaintiff-Relator, were instructed to deliver the message that, "Because Zyprexa treats both symptoms of elevated mood and psychosis, it helps you restore calm to the resident, the staff and even the other residents- the environment will be less disruptive since the resident will be calm instead of yelling, 'Help me-help me.'"

133. Further, on the cover of later versions of the Zyprexa LTC Rose detail piece, along with the symptoms and behaviors, Lilly finally incorporated the language, "ZYPREXA is indicated for the treatment of" and then lists the two approved indications for use for Zyprexa, schizophrenia and acute bipolar mania. Exhibit "G."

134. Among the other duplicitous sales tactics implemented by Lilly at the corporate level involved serious violations of the confidentiality of protected health information safeguarded by the HIPAA regulations as well as breaches of the doctor-patient

privilege.

135. Although Lilly LTC salespersons were evaluated on total Zyprexa sales revenues rendering prescribing physicians, the LTC pharmacies, Lilly LTC sales representatives' relationships with LTC pharmacies were nonetheless pivotal in successfully promoting Zyprexa within the LTC context.

136. Indeed, LTC pharmacies arrange for and bill the State of California' for the drugs prescribed by physicians to LTC facility residents. LTC pharmacies are known as 'closed-door' pharmacies. Closed-door pharmacies are full-service pharmacies, but which exclusively provide prescription drug delivery services to residents of LTC facilities.

137. LTC pharmacies regularly bill Government-funded healthcare plans such as Medicaid for medications prescribed by medical professionals working onsite at the nursing homes.

138. When a patient in a nursing home requires a prescription medication, physicians give written or verbal prescription orders for their patients to nurses. The nurses transmit the prescription orders verbally or by facsimile to the responsible LTC pharmacy clerical data entry personnel to be entered into the LTC pharmacy's computerized order entry system.

139. Once a physician's prescription order is processed in the LTC pharmacy's order entry system, a pharmacist fills the prescription based on the physician's request and the medication is then shipped to LTC skilled nursing home facility where the patient resides.

140. Once the LTC has filled and shipped a prescription, the LTC pharmacy prepares a claim for submission to the Government, including the State of California, seeking reimbursement for the cost of the prescription drug.

141. Lilly knew that the vast majority of elderly LTC residents rely upon, *inter alia*, Medicare and Medicaid to fund in whole or in part their prescription drug costs.

142. Since LTC pharmacies play an integral role in the delivery of prescription drugs to LTC residents, LTC pharmacies were also "clients" of LTC sales representatives

which were targeted for Zyprexa off-label marketing, albeit less frequently than the physicians who are writing the prescriptions.

143. To identify and target the most influential doctors, Lilly encouraged LTC representatives to develop personal relationships with the LTC pharmacies to gain access to the pharmacies' local prescribing data.

144. In addition, LTC pharmacies provide consultant pharmacist services to the LTC facilities they service. Such consultant pharmacists work closely with physicians writing orders in LTC facilities to purported "educate" LTC physicians about prescription alternatives.

145. Because of the significant influence LTC pharmacies play in the prescribing decisions of LTC physicians, Plaintiff-Relator made once monthly sales calls to LTC pharmacies in her territory to ensure the pharmacies encouraged the use of Zyprexa in the facilities they service. Plaintiff-Relator specifically recalls making sales calls to LTC pharmacies to combat financially-incentivizing rebate agreements the LTC pharmacies had negotiated with Janssen, the manufacturer of Zyprexa's competitor Risperdal. Such rebate agreements made it *profitable* for the LTC pharmacy to use its consulting pharmacists power and influence to push LTC physicians to use Risperdal over Zyprexa.

146. Plaintiff-Relator and the LTC sales division generally were also instructed and trained on how to obtain Drug Utilization reports, also known by the acronym "DURs," from the LTC skilled nursing home executive staff. See Exhibit "G."

147. A "Drug Utilization Report" is a report delineating protected health information detailing which patients were taking which drugs and which physician was prescribing those drugs.

148. Lilly enforced this directive by tracking LTC sales representatives' success rates in obtaining the coveted DUR reports. See e.g. Exhibit "H."

149. To keep the LTC sales representatives across the nation abreast of Zyprexa LTC sales as well as successful LTC promotional tactics, Lilly disseminated a LTC Best Practices Newsletter 4 times a year. *Id.*

150. The LTC Best Practices Newsletter is packed with evidence and admissions of Lilly's unlawful LTC off-label marketing campaign. *Id.* It openly addresses Lilly's improper expectation that Lilly LTC sales representatives gain access to protected confidential patient information (i.e. DURs), instructs the sales representative to do rounds with the "NH [nursing home] prescriber" – a highly offensive invasion upon the doctor patient privilege, and contains messages from Lilly executives such as Grady Grant and Tom Olinski, Lilly National Sales Directors and Mike Murray – the LTC Western Division Sales Director and identifies LTC top sales performers across the nation to "SELL ZYPREXA!" The Newsletter also features a "Coaches Corner," which provides tips on maximizing LTC sales of Zyprexa. In the 2003 Winter edition of the Newsletter, the Coaches Corner featured an article by "Wayne Mielke, [the] "Long Term Care Coaching Champ of 2001, on the importance of DUR ATTAINMENT." *Id.*

151. Plaintiff-Relator received the quarterly Lilly LTC Best Practices Newsletter in the course and scope of her Lilly employment.

152. Lilly paid honoraria or speaker fees as part of their overall off label Zyprexa marketing scheme. The payment of and acceptance of the financial incentives in exchange for prescriptions violated the federal Anti-Kickback Statute. See § XI.

153. Lilly management approved huge speaker fee budgets as a means to disguise large payments to physicians who were willing to prescribe Zyprexa off label. Lilly established large budgets for each LTC representative to induce physicians to write off label. The speaking fees were typically $1500 for a "lunch and learn."

154. One method employed by Lilly to conceal kickback payments under the guise of legitimacy was the creation of a "speaker" program. Lilly even established an annual budget for LTC sales representatives to "invest" in speaker fees/honoraria as well as an annual entertainment budget to impress and attract physicians' business.

155. Physicians were even "groomed" by Lilly to be speakers by attending all-expense paid speaking seminars in resort-like atmospheres. These seminars were in truth designed to market Zyprexa, not to provide speaker training. For large volume prescribers,

regardless of whether they exhibited a shred of public speaking acumen, after the seminar such physicians were retained and paid handsomely to speak about Zyprexa.

156. The speaking engagements were frequently a mere sham, indeed, Plaintiff-Relator has personal knowledge that such Lilly-paid speakers were even paid to give pointless presentations to their colleagues at the healthcare facility with which they were affiliated.

157. Such thinly-veiled kickback payments were made with the intent that in return, the paid physician would prescribe Zyprexa for symptoms and illnesses that were unrelated to schizophrenia and bipolar disorder to the frail elderly population. Lilly LTC sales representatives used their improper access to DURs to identify physicians to solicit to enter into unlawful financial relationships.

158. Plaintiff-Relator has personal knowledge that Lilly established similar illegal referral relationships with health care providers throughout the United States.

159. Sales representatives, including Plaintiff-Relator, were instructed by Lilly on implementing "Peer-to-Peer Programs" intended on having paid physicians lecture on designated topics, including off-label topics. Typically, sales representatives, including Plaintiff-Relator, would organize continuing medical education ("CME") programs and offer these programs to their physician customers.

160. By way of example, one such program was "FDA Regulated Programs (Promotional)" wherein the sales representative selects a program topic and a physician under contract with Lilly Lecture Bureau. If the chosen speaker is not under contract, he or she must sign a contract to speak about Lilly's products. See Exhibit "I." The Sales representative submits a speaker payment request to Lilly's Lecture Bureau.

161. To complete the payment process to physicians, Plaintiff-Relator would contact the Lilly Lecture Bureau and the Lilly Lecture Bureau arranged for the check to be sent, typically directly to the lecturing physician. See Exhibit "J."

162. Lilly's Peer to Peer Programs Implementation Guides stresses that the "program time should be balances equally with entertainment time." See Exhibit "K."

Further, the sales representative was instructed to pre-set menus and "pre-select wine list and order group appetizers." *Id.*

163. Another example of a Lilly Peer to Peer Program is the Independent Scientific Exchange (Non promotional Program). This program is ostensibly initiated by the medical institution. The institution contacts the sales representative or Lilly Lecture Bureau directly. Then, Lilly's Lecture Bureau sends the specific institution their "grant request letter." See Exhibit "L." The grant request may contain a request for an honorarium to speak, as well as a request for food, beverages, travel and other expenses. LLB sends grant checks to the institution or physician within 7 days after completion of the program, and sometimes prior to the program. *Id.*

164. Further, by way of example, sales representatives could also initiate "Customer Entertainment" as a Peer to Peer Program. The sales representative invites customer physicians to specific events (i.e., sporting events, concerts, theater or dinners). If the incentive of choice was a dinner, the sales representatives were instructed to select the best items on the menu and select a red and white wine for the table." See Exhibit "M."

165. Lilly's routine practice of paying kickbacks was intended to and did amplify physicians' off-label overutilization of Zyprexa for their patients.

166. Lilly knew that the payments constituted kickbacks in reckless disregard of the law. Lilly was also acutely aware that the safe harbors established by the HHS did not cover the exorbitant payments being made. Lilly intended these payments to encourage Zyprexa overutilization in off-label demographics.

*2) Illegal Off-Label Marketing to Primary Care Physicians*

167. Lilly's national off-label Zyprexa marketing campaign targeting primary care physicians ("PCPs") was designed to make Zyprexa part of the everyday prescribing habits of not only LTC physicians treating the elderly, but also PCPs in their office practices.

168. In order to grow Zyprexa market share sales and surpass competing antipsychotics such as Risperdal, Lilly undertook a scheme to market and promote Zyprexa

for off-label purposes beyond LTC, Lilly concomitantly launched a marketing campaign targeting PCPs. The campaign was designed to "educate" PCPs about which patients they regularly see in their practices who present with symptoms treatable with Zyprexa, *i.e.*, albeit off-label use. Lilly's goal being to make Zyprexa the cornerstone of PCPs everyday prescribing habits.

169. Similar to the LTC sales message, Lilly's PCP off-label Zyprexa promotional campaign focused on symptoms, not diagnoses. To achieve this goal, Lilly PCP sales representatives were trained to deliver a Zyprexa marketing message that centered on symptoms associated with mood, thought, and behavioral disturbances.

170. Lilly targeted PCPs because of the fundamental role PCPs play in patient care and in prescribing drugs to treat a multitude of symptoms, thereby maximize profits and growing market share. In addition, Lilly marketed Zyprexa to primary care physicians for non-indicated uses, because Lilly's marketing studies demonstrated that PCPs generally had less awareness of Lilly's indicated uses and treatment-emergent side effects. Lilly sales material encouraged representatives to promote Zyprexa as a "safe, gentle psychotropic" suitable for people with mood-related symptoms.

171. Lilly PCP sales representatives were trained and instructed to market Zyprexa to PCPs by suggesting that there were a plethora of patients in the physician's practice exhibiting "irritability," "disruptive behavior," "poor sleep," "elevated mood," "depressed mood," "anxiety" and "irregular sleep patterns" and that Zyprexa is a safe and efficacious drug to treat such symptoms.

172. Just as it did for the LTC sales force, Lilly created several promotional caricatures tailored to market Zyprexa to PCPs. The primary PCP caricature Plaintiff-Relator became familiar with is "Donna." "Donna" is a mother of two children in her early 30's who is distracted and depressed and these symptoms are interfering with her daily life. Perhaps Donna has been prescribed drugs that treat depression. Lilly sales representatives were trained and instructed to encourage PCPs with "Donnas" in their practice to prescribe Zyprexa, although she has not been diagnosed with either bipolar mania or schizophrenia.

173. Lilly developed Donna knowing that millions of people fit Donna's broadly defined profile and who are not psychotic, schizophrenic, or bipolar. This way, Lilly could accomplish its primary goal to drive off-label sales of Zyprexa by causing as many unsuspecting adult patients on Zyprexa as possible.

174. Plaintiff-Relator has personal knowledge that Lilly's promotion of Zyprexa to PCPs, including her presence in PCP physicians' offices during a Lilly PCP sales representative's sales call.

175. Each LTC sales representative's territory "overlapped" with a Zyprexa PCP sales representative. Lilly expected its LTC representatives to coordinate with his or her overlap.

176. Accordingly, Plaintiff-Relator periodically made joint sales calls to PCPs who also treated LTC residents with her "overlap." During these joint Zyprexa sales calls, Plaintiff-Relator witnessed her Lilly PCP overlap deliver the Zyprexa off-label PCP marketing message designed to promote Zyprexa's superior efficacy and safety for treating adult patients who presented with symptoms relating to mood, anxiety, and depression, while omitting that Zyprexa is not indicated for the treatment of such symptoms not attendant to the diagnosis of bipolar disorder or schizophrenia.

177. Plaintiff-Relator witnessed the PCP overlap use, wherein the PCP sales representatives referred and relied upon the Donna profile to promote Zyprexa off-label for depression and mood disorders. At no time did the PCP sales representative initiate any discussion about Zyprexa's lack of indication for the treatment of such symptoms in patients not diagnosed with schizophrenia or bi-polar disorder.

178. Lilly's efforts to promote Zyprexa for use as a general mood stabilizer in the treatment of depression have resulted in billions of dollars of revenue for the company.

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## X. LILLY CAUSED THE SUBMISSION OF FALSE CLAIMS FOR ZYPREXA REIMBURSEMENT TO BE SUBMITTED BY LONG TERM CARE PHARMACIES

### A. Zyprexa Prescribed Off-label to LTC Residents Was Ineligible for Reimbursement by the Medicaid Program

179. Prior to the enactment of the Medicare Part D program, Medicaid purchased an estimated 80-90% of atypical antipsychotic prescriptions. Of the top 30 drugs by total US revenue, Zyprexa is the most expensive. As detailed herein, the FDA defines off-label use as indications, dosage, form, dose regimen, population or other use parameter not mentioned in the approved labeling.

180. Because prescriptions for off-label uses generally are not eligible for reimbursement, under Medicaid and Medicare regulations, submission of a claim for reimbursement for a drug prescribed off-label constitutes a false claim for the purposes of the State of California's False Claims Act. While it is a pharmacy, by virtue of the reimbursement system, which unwittingly submits the false prescription drug claim, the person or persons who knowingly cause(s) such a claim to be presented to the State of California, including the State of California, is liable under the law. Here, Lilly's California False Claims Act violations arise from its successful attempts to induce LTC pharmacies to unwittingly defraud the State of California.

181. Lilly knew that medically unnecessary, off-label Zyprexa prescriptions were ineligible for Medicaid reimbursement and that its activities would, in fact, cause numerous ineligible prescriptions to be submitted to Medicaid and Medicare by the LTC pharmacies which arranged for pharmaceutical benefits to LTC patients.

182. The unwitting participation of the LTC pharmacies in the submission of false claims was not only foreseeable; it was an intended consequence of Lilly's scheme of fraud.

183. Absent Lilly's intentional, illegal off-label marketing in the LTC demographic, and its unlawful financial relationships with doctors, Zyprexa would not have been prescribed off-label. Lilly's off-label marketing programs have been extremely

successful, leading to the submission of claims to the Medicare and Medicaid programs for medically unnecessary and imprudent prescriptions which otherwise would not have been paid by Medicare and Medicaid.

184. Each Zyprexa claim submitted to the State of California for Zyprexa prescribed for an off-label use not only violates Medicare payment rules, but constitutes the submission of a fraudulent claim redressable by California's False Claims Act, Cal. Gov. Code §§ 12650 et seq.

185. The remedial provisions of the California's False Claims Act is the necessary vehicle to obtain redress for the substantial economic harm suffered by Medi-Cal as a result of the millions of dollars of Zyprexa reimbursement claims caused to be written and submitted by enrolled Medi-Cal pharmacy benefits providers to the State of California as a direct and foreseeable result of Lilly's illegal off-label marketing campaign.

186. Lilly's wanton misconduct has been ongoing since at least 2001.

## XI. THE CALIFORNIA FALSE CLAIMS ACT

187. The California False Claims Act, Cal. Gov. Code §§12650 et seq., provides, in pertinent part that a person is liable to the State of California for a civil penalty of up to $10,000, plus not less than two times and not more than three times the amount of damages which the State of California sustains because that person, *inter alia*,:

(a) Liability for certain acts. Any person who—

(1) Knowingly presents, or causes to be presented, to an officer of the state or of any political subdivision thereof, a false claim for payment or approval;

(2) Knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state or by any political subdivision;

(3) Conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision;

(4) Has possession, custody, or control of public property or money used or to be used by the state or by any political subdivision and knowingly delivers or causes to be delivered less property than the amount for which the person receives a certificate or receipt;

(5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the state or by any political subdivision and knowingly makes or delivers a receipt that falsely represents the property used or to be used;

(6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any person who lawfully may not sell or pledge the property;

(7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision; or

(8) Is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

188. Under § 12650(b) (1) – (3) of California's False Claims Act, "Knowing" and "knowingly" mean that a person, with respect to information, does any of the following: (1) Has actual knowledge of the information, (2) Acts in deliberate ignorance of the truth or falsity of the information or (3) Acts in reckless disregard of the truth or falsity of the information. Proof of specific intent to defraud is not required.

## XII. DEFENDANT LILLY'S VIOLATIONS OF THE FEDERAL AND CALIFORNIA ANTI-KICKBACK STATUTES CAUSED FALSE CLAIMS TO BE SUBMITTED TO THE GOVERNMENT

### A. Federal Anti-Kickback Statute Prohibitions

192. The Medicare and Medicaid Fraud and Abuse Statute (Statute) was first

enacted under the Social Security Act in 1977. The Statute imposes criminal penalties on whomever violates the Anti-Kickback Provision and states in relevant part, whoever knowingly and willfully offers or pays remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person:

> (A) to refer an individual to a person for the furnishing of or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase or lease, order or arrange for or recommend purchasing, leasing, or ordering any good, facility, service or item for which payment may be made in whole or in part under a Federal Health care program.

42 U.S.C. § 1320a-7b(b)(2)(A) & (B).

193. By its terms, the Federal Medicare and Medicaid Anti-Kickback Statute prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

194. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

195. A violation of the AKS arises if *one purpose* of the payment was to induce future referrals even if the payment was also intended to compensate for professional services. *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989).

196. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the State of California because, as is alleged herein, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by physicians, limit patient options and lead to higher federal and state payments for prescription drug benefits. The Anti-Kickback Statute was promulgated to thwart such dangerous practice of medicine.

197. The remuneration paid by Lilly and accepted by participating Med-Cal

physicians all across the country, as alleged in detail *supra*, fit squarely within the AKS's definition of illegal remuneration.

198. As alleged herein, in violation of the AKS, Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa to LTC patients, children and adults, notwithstanding Lilly's knowledge of the prohibitions of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government.

199. Lilly entered into unlawful inducement relationships in violation of the Anti-Kickback Statute with LTC physicians, PCPs, pediatric physicians and other medical professionals nationwide.

200. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Lilly.

201. Lilly prevented the State of California from knowing of the underlying violations of the federal and California AKS violations by concealing its illegal agreements with Medi-Cal participating providers as well as concealing the exchange of illegal remuneration pursuant thereto.

**B. Violations of California's Health & Safety Comprehensive Compliance Program**

202. California's Health and Safety Code §§ 119400-119402 relates to prescription drug and medical device marketing practices. The California Marketing Compliance Law ("CMCL") requires pharmaceutical companies and medical device manufacturers to adopt Comprehensive Compliance Programs (CCPs) that meet the standards set forth in the compliance guidance for pharmaceutical companies published by the Department of Health and Human Services' Office of Inspector General (OIG). CA Health & Safety Code §119400(a). These compliance programs must also contain provisions concerning their interactions with medical and health professionals, and adopt limits on gifts to such

professionals. Finally, the CMCL requires covered companies to make certain compliance declarations publicly. California Health and Safety Code §§ 119400-119402.

203. The CMCL applies to entities "engaged in the production, preparation, propagation, compounding, conversion, or processing of dangerous drugs, either directly or indirectly, by extraction from substances of natural origin or independently by means of chemical synthesis or by a combination of extraction and clinical synthesis." California Health and Safety Code § 119400(c). The law also states that "pharmaceutical company" also means "an entity engaged in the packaging, repackaging, labeling, re-labeling, or distribution of dangerous drugs," as well as "a person who engages in pharmaceutical detailing, promotional activities, or other marketing of a dangerous drug in ... [California] on behalf of a pharmaceutical company." California Health and Safety Code § 119400(c).

204. The CMCL also regulates interactions by drug and device companies with "medical or health professionals," which are defined as persons licensed by state law to prescribe drugs for human patients, a medical student, or a drug formulary committee member. California Health and Safety Code § 119400(b).

205. Drug and device manufacturers must adopt a Comprehensive Compliance Program that is "in accordance with" the Office of Inspector General's 2003 Compliance Program Guidance for Pharmaceutical Manufacturers. California Health and Safety Code § 119402(a).

206. The CMCL requires manufacturers to implement "a specific annual dollar limit on gifts, promotional materials, or items or activities" that the manufacturer may provide to medical or health care professionals, in accordance with the OIG Compliance Guidance and the Pharmaceutical Research and Manufacturers of America in July 2002 (the PhRMA Code). California Health and Safety Code § 119402(c)-(d).

207. The CMCL requires that manufacturers "annually declare" in writing that they are in compliance with their own CCP and with the CMCL. California Health and Safety Code § 119402(e).

208. By its terms, the California's Health and Safety Code §§ 119400-119402

prohibits certain conduct involving improper payments in connection with the delivery of goods or services, including prescription drugs, covered by Medicare, Medicaid and other federal health care programs.

194. Illegal payments or solicitations of payments include those in cash or in kind, *i.e.*, goods, those made directly or indirectly, and those made overtly or covertly.

195. Such illegal inducement relationships between drug companies and physicians endanger patients and harm the State of California because, as here, they encourage unnecessary treatments, contaminate the free exercise of medical judgment by providers, limit patient options and lead to higher federal and state payments for prescription drug benefits. California's Health and Safety Code §§ 119400-119402 was promulgated to thwart such dangerous practice of medicine.

197. The remuneration paid by Lilly and accepted by physicians all across the country, including the State of California, as alleged in detail *supra*, are precisely the type of conduct California's Health and Safety Code §§ 119400-119402 aims to prohibit.

198. As alleged herein, in violation of California's Health and Safety Code §§ 119400-119402, Lilly paid, and physicians accepted, unlawful remuneration, including cash payments thinly-veiled as "speaker fees," honoraria, unrestricted educational grants and other gratuities as *quid pro quo* for volume prescription writing of Zyprexa to LTC patients, children and adults, notwithstanding Lilly's knowledge of the prohibitions of offering, paying or receiving items of value in exchange for arranging the purchase of any good paid for in whole or in part by the federal government and the State of California.

199. Lilly entered into unlawful inducement relationships in violation of California's Health and Safety Code §§ 119400-119402 with LTC physicians, PCPs, pediatric physicians and other medical professionals nationwide.

200. Although "safe harbor" regulations exist to protect certain relatively innocuous and even beneficial commercial arrangements, no such provision protects the kickbacks paid by Lilly.

201. Lilly prevented the State of California from knowing of California's Health

and Safety Code §§ 119400-119402 violations by concealing such agreements.

**C. Defendant Lilly's Anti-Kickback Statute Violations and Violations of California's Health and Safety Code §§ 119400-119402 are Predicate Acts Giving Rise to Liability Under the State and Federal False Claim Acts**

202. The Anti-Kickback Statute and California's Health and Safety Code §§ 119400-119402 work hand in glove with the False Claims Act. As a matter of law, violations of the AKS and California's Health and Safety Code §§ 119400-119402 state a cause of action under the False Claims Act. Indeed, compliance with the AKS, as well as all other relevant laws and regulations, is a condition of payment by Medicaid for prescription drug claims. 42 U.S.C. §1320a-7b(b).

203. Thus, where conduct that violates the Anti-Kickback Act or California's Health and Safety Code §§ 119400-119402 results in goods and services (here, Zyprexa) provided to Medi-Cal beneficiaries, that good or service is *ineligible* for reimbursement under Medi-Cal payment rules and federal law.

204. Thus, as a matter of law, prescription drugs and other products purchased in violation of the AKS or California's Health and Safety Code §§ 119400-119402 are ineligible for Medi-Cal reimbursement. By and through the covert payment of illegal kickbacks, Lilly defrauded, *inter alia*, Medi-Cal -participating pharmacies into presenting reimbursement claims for Zyprexa to the State of California containing the false certification that the claim was submitted in compliance with the AKS or California's Health and Safety Code §§ 119400-119402 and other applicable regulations.

205. The State of California would appropriately have denied Zyprexa reimbursement claims if it had knowledge that the Zyprexa prescription written which gave rise to the claim for reimbursement was the product of an illegal kickback arrangement.

206. Defendant Lilly, acting in concert with physicians, caused, *inter alia*, Medicaid-participating pharmacies all across the country to submit claims that were rendered ineligible for reimbursement by Lilly's violations of the AKS and California's Health and Safety Code §§ 119400-119402 as well as caused such pharmacies to explicitly falsely certify

that they were acting in compliance with all applicable laws and regulations, including the AKS, for each and every claim the pharmacies submitted. The pharmacies' certifications Lilly caused to be submitted to the State of California, however, were false when made.

207. Such pharmacies reasonably and justifiably relied upon the validity and medical appropriateness of the Zyprexa prescriptions.

208. Lilly's illegal scheme had one intended purpose and result – increasing Zyprexa profits – and therefore certified claims for Zyprexa prescriptions instead of cheaper alternatives were submitted to the State of California for payment by pharmacies throughout the nation. Accordingly, at all times relevant to the Complaint, Lilly acted with the requisite scienter.

209. The result of the Lilly's scheme was a dramatic increase in the number of claims submitted to the State of California for the higher priced Zyprexa, which led to dramatically higher revenue for Lilly. Lilly's increased revenues, and the correspondingly-increased cost to the Government healthcare programs, were the direct, intended, and foreseeable result of the unlawful kickbacks payments made by Lilly to LTC physicians, PCPs and pediatric physicians.

210. Lilly's liability under §§ 3729(a)(1) and (a)(2) of the Federal False Claims Act, §§ 68.082(a) and California False Claims Act, Cal. Govt. Code §12650 *et seq.* arises from the drug company's overt and willful participation in causing the basis for false claims to be made through the establishment of an illegal and corrupt financial relationships.

211. Lilly's conduct is also punishable under §12651 (a)(3) of the Federal False Claims Act, and California False Claims Act, Cal. Govt. Code §12650 *et seq.*, for entering into an unlawful conspiracies with the intent to defraud the Government.

**FIRST CAUSE OF ACTION**
**California False Claims Act**
**Ca. Government Code §12650 *et seq.***

212. Plaintiffs reallege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

213. This Count is brought by Plaintiff-Relator Vicente in the name of the State of California under the *qui tam* provisions of the California False Claims Act, California Government Code §12651(a).

214. Defendant Lilly at all times relevant to this action sold and marketed, and continues to sell and market, pharmaceuticals, including Zyprexa, in the State of California.

215. A significant percentage of patients who use or have been prescribed Zyprexa off-label for non-medically necessary uses as a result of Lilly's unlawful off-label marketing campaign are persons whose prescriptions are paid for in whole or in part by Medi-Cal or other State funded healthcare programs.

216. At all times relevant and material to this Complaint, Lilly has induced a misallocation of California's funds through a pattern of fraudulent conduct, as alleged herein. Lilly intentionally concealed its campaign to market Zyprexa in California and throughout the United States for un-approved indications and medically unnecessary uses for the purpose of, and with the effect of, unlawfully increasing purchases of Zyprexa prescriptions by Medi-Cal that would not have funded but for Lilly's active concealment of its unlawful Zyprexa off-label marketing campaign.

217. By the conduct alleged in this Complaint, Lilly has knowingly and foreseeably caused the submission false claims for payment or approval that Lilly knew to be ineligible for reimbursement and the cost of which would be borne by California by and through, *inter alia*, Medi-Cal, to be presented to officers and employees of the State of California. Defendant has also caused false records and statements to be submitted to officers and employees of the State of California to get its false claims paid.

218. Lilly's conduct includes its deceptive and illegal scheme to expand off-label use of Zyprexa by, *inter alia*, 1) marketing Zyprexa in a misleading and/or disingenuous way for off-label uses and populations to physicians in the long term care and primary care markets and 2) orchestrating a kickback scheme pursuant to which, in sum, it paid physicians in cash and in kind in exchange for writing off-label prescriptions of Zyprexa. As a result, the California has paid false claims submitted for the Zyprexa drugs by Medi-

Cal participating pharmacies, resulting in great financial loss to the State.

219. Lilly's conduct constitutes the intentional violation of the California False Claims Act and other laws.

220. The claims for Zyprexa caused to be submitted by Lilly constitute false claims because, *inter alia*, Medi-Cal reimbursement is not available for non-medically accepted indications or non-medically necessary uses of prescription drugs as alleged herein.

221. By virtue of the above-described acts, Lilly has also knowingly and intentionally conspired to, and caused false claims for payment to be submitted for Zyprexa from the implementation of its kickback scheme as well as caused false records and statements to be submitted to get false Zyprexa claims paid. Lilly's kickback scheme violated the Federal Anti-Kickback Statute and the analogous law of the State of California and has thereby caused the submission of false claims and records to Medi-Cal.

222. It was the intended and foreseeable effect of Lilly's kickback scheme to cause pharmacies to routinely submit thousands false claims requesting reimbursement for expensive Zyprexa prescriptions.

223. The amounts of the false or fraudulent claims and records or statements caused by Lilly to be submitted to Medi-Cal were material.

224. Plaintiff California, being unaware of the falsity of the claims and statements or records caused to be made by Defendant Lilly as alleged herein, and in reliance on the accuracy thereof, paid and may continue to pay for off-label prescriptions of Zyprexa.

225. All unlawful conduct described above may have continued after Plaintiff-Relator's voluntary decision to seek alternative employment.

226. By reason of the conduct described above, California has been damaged in an amount that is believed to be in excess of tens of millions of dollars annually for claims submitted for Zyprexa in Northern California alone.

227. California is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty of up to $10,000 for each ineligible claim

submitted to Medi-Cal for payment.

## SECOND CAUSE OF ACTION

**Conspiracy to Submit False Claims in Violation of the California False Claims Act Ca. Gov't Code §12651(a)(3)**

228. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

229. By entering into illegal kickback agreements as detailed herein, Defendant Lilly conspired with healthcare providers to defraud the State of California causing the submission of false claims for Zyprexa. At all times relevant to the complaint, Defendant Lilly knowingly violated the Anti-Kickback Statute.

230. As a result of the claims for reimbursement Defendant Lilly caused to be submitted to Medi-Cal, which were falsely certified compliant with federal and state Medicaid law and regulation as a condition of payment to LTC pharmacy benefit providers, California regularly made payments to pharmacies for Zyprexa.

231. The amounts of the false or fraudulent claims to the State of California were material.

232. Plaintiff State of California, being unaware of the falsity of the claims and/or statements made by Defendant Lilly, and in reliance on the accuracy thereof paid and may continue to pay for Zyprexa. All unlawful conduct described above may have continued after Plaintiff-Relator voluntary left Lilly's employ.

233. The State of California is entitled to multiple damages under the California False Claims Act, to be determined at trial, plus a civil penalty of up to $10,000 for each ineligible claim submitted to Medi-Cal for payment.

## THIRD CAUSE OF ACTION

**(Violation of Business & Profession Code § 17200)**

234. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

235. Plaintiffs are informed and believe and allege that Lilly, by the acts and misconduct alleged herein, violated Business and Professions Code sections 17200.

236. California Business & Professions Code Section 17200 provides that unfair competition shall mean and include "all unlawful, unfair or fraudulent business practices and unfair, deceptive, untrue or misleading advertising."

237. The acts and practices described herein were and are likely to mislead the general public and therefore constitute unfair business practices within the meaning of Business & Professions Code Section 17200. The acts and untrue and misleading advertising set forth in presiding paragraphs are incorporated by reference and are, by definition, violations of Business & Professions Code Section 17200. This conduct includes, but is not limited to:

a. Representing to the State of California and the general public that Zyprexa was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the State of California and the general public that Zyprexa has a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that the use of Zyprexa was safe for human use, had fewer side effects and adverse reactions than other methods for treating schizophrenia and bi-polar disorder, constituted a convenient, safe form for treating schizophrenia and bi-polar disorder, even though the Defendant Lilly knew these to be false, and even though the Defendant Lilly had no reasonable grounds to believe them to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Zyprexa; and

d. Issuing promotional literature deceiving potential users of Zyprexa by relaying positive information and manipulating statistics to

suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Zyprexa.

238. These practices constitute unlawful, unfair and fraudulent business acts or practices, within the meaning of California Business & Professions Code Section 17200, as well as unfair, deceptive, untrue and misleading advertising as prohibited by California Business & Professions Code Section 17500, as set forth herein.

239. The unlawful, unfair and fraudulent business practices of Defendant Lilly described above present a continuing threat to members of the public in that Defendant Lilly continues to engage in the conduct described therein.

240. As a result of their conduct described above, Defendant Lilly has been unjustly enriched. Specifically, Defendant Lilly has been unjustly enriched by receipt of billions of dollars in ill-gotten gains from the sale and prescription of Zyprexa in California, and other states, sold in large part as a result of the acts and omissions described herein.

241. Because of the fraudulent misrepresentations made by Defendant Lilly as detailed above, and the inherently unfair practice of committing a fraud against the State of California and the general public by intentionally misrepresenting and concealing material information, the acts of Defendant Lilly described herein constitute unfair or fraudulent business practices.

242. Plaintiffs, the State of California and Plaintiff-Relator, pursuant to California Business & Professions Code Section 17203, seek an order of this court compelling the Defendant Lilly to provide restitution, and to disgorge the monies collected and profits realized by Defendant Lilly, as a result of their unfair business practices.

243. Defendant Lilly's acts were willful, wanton, reckless and fraudulent; hence, the State of California and Plaintiff-Relator are entitled to exemplary damages, inter alia.

**WHEREFORE**, Plaintiffs demand judgment against Defendants and seek compensatory damages, disgorgement, restitution, and exemplary and punitive damages together with interest, the costs of suit, attorneys' fees and such other and future relief as

the Court deems just and proper.

**FOURTH CAUSE OF ACTION**

**(Violation of Business & Profession Code § 17500)**

244. Plaintiffs re-allege and incorporate by reference all of the foregoing paragraphs as if fully set forth herein.

245. Plaintiffs are informed and believe and thereon allege that Defendants, by the acts and misconduct alleged herein, violated Business & Professions Code Section 17500.

246. Plaintiffs hereby seek restitution, as well as and punitive damages against Defendant Lilly for their violations of section 17500.

247. California Business & Professions Code section 17500 provides that it is unlawful for any person, firm, corporation or association to dispose of property or perform services, or to induce the public to enter into any obligation relating thereto, through the use of untrue or misleading statements.

248. At all times herein mentioned, Defendant Lilly has committed the acts of disseminating untrue and misleading statements as defined by Business & Professions Code Section 17500 by engaging in the following acts and practices with intent to induce members of the public to purchase and use Zyprexa:

a. Representing to the State of California and the general public that Zyprexa was safe, fit and effective for human consumption, knowing that said representations were false, and concealing from the State of California and the general public that Zyprexa has a serious propensity to cause injuries to users;

b. Engaging in advertising programs designed to create the image, impression and belief by consumers, physicians and others that the use of Zyprexa was safe for human use, had fewer side effects and adverse reactions than other methods for treating mental illness, constituted a convenient, safe form for treating mental illness, even though the Defendant

Lilly knew these to be false, and even though the Defendant Lilly had no reasonable grounds to believe them to be true;

c. Purposely downplaying and understating the health hazards and risks associated with Zyprexa; and

d. Issuing promotional literature deceiving potential users of Zyprexa by relaying positive information and manipulating statistics to suggest widespread acceptability, while downplaying the known adverse and serious health effects and concealing material relevant information regarding the safety of Zyprexa.

249. The foregoing practices constitute false and misleading advertising within the meaning of California Business & Professions Code Section 17500.

250. As a result of its false and misleading statements described above, Defendant Lilly has been and will be unjustly enriched. Specifically, Defendant Lilly has been unjustly enriched by receipt of billions of dollars from the sale and prescription of Zyprexa in California and other states, sold in large part as a result of the false or misleading statements described herein.

251. Pursuant to California Business & Professions Code Section 17535, Plaintiffs seek an order of this court compelling Defendant Lilly to provide restitution, and to disgorge the monies collected and profits realized by Defendant Lilly, as a result of their unfair business practices, and injunctive relief calling for Defendant Lilly to cease such unfair business practices in the future.

## JURY DEMAND

443. Plaintiffs demand trial by jury on all claims.

**WHEREFORE**, Relator-Plaintiff, on behalf of herself, and the State of California and the State of California, requests the following relief:

(a) Judgment against Defendant Lilly in the amount of three (3) times the amount of damages the State of California has sustained because of Defendant Lilly's actions, plus a civil penalty of $10,000.00 for each action in violation California False

Claims Act, Cal. Gov. Code §§ 12650 et seq., and the appropriate fines and penalties for violating the protective California laws applicable to the fraudulent and false conduct and the cost of this action with interest;

(b) That Plaintiff-Relator be awarded the maximum amount allowed pursuant to the California False Claims Act, Cal. Gov. Code §12651(a), plus interest, and all relief to which she is entitled pursuant to said laws;

(c) That the Plaintiff-Relator be awarded all costs incurred, including reasonable attorneys' fees;

(d) In the event that the State of California proceed with this action, Plaintiff-Relator Vicente, be awarded an appropriate amount for disclosing evidence or information that the State of California did not possess when this action was brought to the government. The appropriate amount is not greater than twenty-five percent (25%) of the proceeds of the action or settlement of a claim. The amount awarded to Plaintiff-Relator also includes the results of government actions or settlement of claims resulting from the expansion of claims through the government's further investigation directly generated from or attributable to Plaintiff-Relator's information; and,

(e) Such other relief as this Court deems just and appropriate.

DATED: May 11, 2007.

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